

# An observational study on acceptability, palatability, and safety of *Ayurveda* immunity booster kit for the prevention of COVID-19 in frontline workers in Jaipur, India

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## Abstract

**Background:** National Institute of Ayurveda, Jaipur, India, had distributed *Ayurveda* immunity booster kit (AIBK) (prepared at own pharmacy and comprising *Chyawanprasha* – 300 g, *Vyadhi Kshamatva Kwatha* – 300 g, and *Vyadhi Kshamatva* capsule – 30 g) for 15 days among the health-care workers, sanitation workers, and security and police staff engaged in the containment zones for prevention of COVID-19. **Aim:** The aim of present study was to explore the medication that may be effective in prevention of the COVID-19. Hence, this study was done to assess the compliance of these medicines and their effects in the prevention of COVID-19. **Methods:** One thousand seven hundred and fourteen frontline workers were provided with the AIBK for 15 days from April 24, 2020, to June 27, 2020. Data of frontline workers who had participated in AIBK and completed the treatment regimen with 2 weeks of follow-up after treatment with complete available data for safety, palatability, efficacy, and compliance were included in the study. Any adverse event needing hospitalization or medication, drug compliance and palatability, and appearance of the symptoms of COVID-19 or testing positive for COVID-19 were the outcome measures. **Results:** Out of 1714 participants, 1003 participants were found to be eligible for this analysis. The median age of these participants was 39 years (range, 19-70), and males accounted for 90.1% (904 of 1003). A total of 7.5% of participants (75 of 1003) reported having adverse events after taking the study treatment. None of the participants reported any serious adverse effects after the administration of the AIBK. The acceptability of the AIBK was as high as 97.4%. None of the participants reported positive for COVID-19 results or COVID-19 symptoms up to 2 weeks of follow-up after completion of the study treatment. **Conclusion:** The acceptability of AIBK is good and indicates its role in the prevention of COVID-19-like illness, hence further randomized control trials or cohort studies can be done to assess the mechanism of action and efficacy of AIBK as the preventive strategy in COVID-19.

**Keywords:** Immunity, prophylaxis, *Vyadhikshamatva*

## Introduction

In December 2019, a sudden public health incidence (the coronavirus disease [COVID-19] epidemic) occurred in Wuhan, China.<sup>[1]</sup> The incidence was the appearance of pneumonia of unknown etiology. Later on, it became evident that the disease is being caused by a pathogenic virus called as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and named as “COVID-19” by the World Health Organization (WHO) on February 11, 2020. The WHO declared COVID-19 a pandemic on March 11, 2020.<sup>[2]</sup> Face mask, sanitization of hand, and social distancing are the established measures for slowing the spread of COVID-19.<sup>[3]</sup>

In May and June 2020, hydroxychloroquine and other drugs were recommended for the prophylaxis to high-risk group individuals by the Indian Council of Medical Research. However, in May and June 2020, the National Institute of

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Health (NIH) COVID-19 treatment guidelines suggested that no existing drug/agent was effective in preventing SARS-CoV-2 infection.<sup>[4]</sup> NIH had also not recommended the use of any agents, including chloroquine, for preexposure prophylaxis (PrEP) or postexposure prophylaxis for the prevention of SARS-CoV-2 infection outside of clinical trials at that time.<sup>[4]</sup> Furthermore, no vaccines were available for the prevention of disease at that time. Various traditional Ayurveda formulations such as *Kwatha* (decoction of medicinal herbs) and herb-mineral compounds were extensively used in India by Ayurveda physicians and government institutions for the prevention of COVID-19. However, their acceptability in population, palatability, and safety was unknown in the context of the prevention of COVID-19. Hence, there was a need to explore these issues for future research purposes. National Institute of Ayurveda, Jaipur, deemed to be a university under the Government of India, also formulated an Ayurveda immunity booster kit (AIBK) (comprising *Chyawanprasha* – 300 g, *Vyadhi Kshamatva Kwatha* – 150 g, and *Vyadhi Kshamatva* capsule – 30 g) and distributed it among frontline workers for the prevention of COVID-19 in Jaipur city and data were collected. It was decided to utilize these data for exploratory analysis. In this present analysis, we have analyzed the participants for safety, drug outcomes in the prevention of COVID-19, and compliance with the AIBK in the participants.

## Methods

### Study design and oversight

This was a retrospective exploratory analysis of the existing data from the participants receiving the AIBK as PrEP for COVID-19. The study was an open-label, non-randomized single-arm self-assessed nondiagnostic survey. AIBK was distributed among frontline workers from April 24, 2020, to June 27, 2020, for PrEP as part of the institution's initiative, and data related to baseline characteristics, information regarding any symptoms after intake of the kit, present health status, medication compliance, and palatability were obtained telephonically by the trained postgraduate students of the institute.

### Participants

Data of the frontline workers were analyzed in this study. These frontline workers included health-care workers, chemists, workers involved in sanitation and cleanliness, and security and police staff engaged in the containment zones or quarantine centers or COVID centers. These individuals were engaged either in the door-to-door screening of the COVID-19 patients or at checking points in containment zones or in sanitation and cleanliness of quarantine centers and COVID centers in Jaipur city, India. These frontline workers were engaged daily for at least 7 h.

### Inclusion criteria

Data of frontline workers who had participated for AIBK and completed the treatment regimen with 2 weeks to 2 months

of follow-up after treatment with complete available data for safety, efficacy, and compliance were included in the study.

### Intervention

The AIBK comprised *Chyawanprasha*, *Vyadhi Kshamatva Kwatha* [Table 1], and *Vyadhikshamatva* capsule. [Table 2] These medicines were prescribed as *Chyawanprasha* 10 g, *Vyadhi Kshamatva Kwatha* 40 ml (10 g of *Yavakuta Kwatha* [crushed into coarse powder] boiled in 160 ml of water and reduced to one-fourth and filtered), and *Vyadhikshamatva* capsule (immune booster capsule) – 1 g 12 hourly for 15 days.

### Setting

Distribution of kits to police personnel was done by the mechanism of obtaining their list with their names and phone numbers from the police commissioner's office, Jaipur, and police stations in the containment zones and providing the kits to their head of department for distribution between these people. Other recruited participants received these kits individually from the deputy medical superintendent office of the National Institute of Ayurveda, Jaipur. A consent form and instruction leaflet describing the method of usage and standard guidelines of preventive care such as hand-wash and masks were provided with AIBK. Contact numbers were also provided to participants for any queries or problems related to AIBK. Telephonically follow-up surveys were done on day 1, day 5, day 10, and day 15 by the trained postgraduate students. Another telephonic survey was done at week 4 and the 2<sup>nd</sup> month by asking about any follow-up testing, illness, or hospitalizations.

When the use of AIBK was started using in these frontline worker, there was no intention to collect the data and analyze it. However, it was decided to analyze as analysis of this larger population would certainly help in getting some conclusion on AIBK. Hence, considering the ethical conduct of any study or survey, we decided to take Ethics Committee's approval. Moreover, we obtained permission from the Institutional Ethics Committee of the National Institute of Ayurveda via letter no. IEC/ACA/2020/3-108 dated June 30, 2020, to analyze these data for safety, documentation of prevalence of COVID-19, and compliance with the AIBK. In this survey, we analyzed only those participants who had completed the 15-day course of AIBK. The lag between the last dose of the medication and the interview date was ranging between 2 weeks and 2 months among different batches of participants. [Table 3] This follow-up period covered the possible incubation period of COVID-19. The safety of the AIBK was analyzed by assessing any serious adverse events needing intensive care or hospitalization. Drug efficacy outcomes were assessed by the presence of COVID-19-like symptoms after taking the AIBK.

### Outcome measures

Any adverse events needing hospitalization or medication, drug compliance, and palatability were the primary outcome measures. Prevention of symptoms of COVID-19 such as fever, cough, breathlessness, or testing positive for COVID-19 was the secondary outcome measure.

**Table 1: Composition of immune booster *Kwatha* (decoction) formulation**

Plant name	Parts used	Proportion	Properties
<i>Giloya</i> ( <i>Tinospora cordifolia</i> (Willd.) Hook. F. and Thoms.)	Stem	One part	Immune modulation and antiviral effect <sup>[5,6]</sup>
<i>Nagarmotha</i> ( <i>Cyperus rotundus</i> L.)	Rhizome	One part	Anti-allergic, anti-arthritic, anti- <i>Candida</i> , anticariogenic, anticonvulsant, antidiarrheal, antiemetic, antihelminthic, antihistamine, antihyperglycemic, antihypertensive, anti-inflammatory, antimalarial, anti-obesity, antioxidant, antiplatelet, antipyretic, antiulcer, antiviral, cardioprotective, cytoprotective, cytotoxic, gastroprotective, hepatoprotective, neuroprotective, ovidical, and larvicidal, wound healing and inhibition of brain Na + K + ATPase activities, antiviral activities <sup>[7,8]</sup>
<i>Triphala</i> ( <i>Terminalia chebula</i> Retz. and Willd.) + ( <i>Terminalia bellirica</i> ROXB.) + ( <i>Emblica officinalis</i> Gaertn.)	Fruit pulp	One part	Immune modulation effects <sup>[9,10]</sup>
<i>Raktachandana</i> ( <i>Pterocarpus santalinus</i> L.F.)	Heart wood	One part	Including anti-oxidative, antidiabetic, antimicrobial, anticancer, and anti-inflammatory properties, and protective effects on the liver, gastric mucosa, and nervous system <sup>[11]</sup>
<i>Tulsi</i> ( <i>Ocimum sanctum</i> L.)	Whole part	One part	Immune modulation <sup>[12]</sup>
<i>Chirayata</i> ( <i>Swertia chirayita</i> Roxb. Ex (Fleming) Karst.)	Whole part	One part	Anti-HBV activities <sup>[13,14]</sup>
<i>Madhuyasti</i> ( <i>Glycyrrhiza glabra</i> L.)	Root	One part	Anticoagulant, antiviral, antioxidant, anti-inflammatory, and having immune modulation activity <sup>[15]</sup>
<i>Kutki</i> ( <i>Picrorhiza kurroa</i> Royle Ex Benth.)	Root	One part	Antioxidant activity <sup>[16]</sup>
<i>Kutaja</i> ( <i>Holarhena pubescens</i> (Buch.-Ham.) Wallich Ex Do)	Stem bark	One part	<i>In vitro</i> antioxidant activity <sup>[17]</sup>
<i>Karanja</i> ( <i>Pongamia pinnata</i> L.)	Seed	One part	Wound healing, antimicrobial and antioxidant potential. Gastroprotective properties antioxidant and H, K-ATPase inhibitor <sup>[18,19]</sup>
<i>Pittapapada</i> ( <i>Justicia procumbens</i> L.)	Whole part	One part	Antidiarrheal, antispasmodic, and bronchodilator activities <sup>[20]</sup>
<i>Bhunyaamalaki</i> ( <i>Phyllanthus niruri</i> Sensu Hook. F. Non Linn. )	Whole part	One part	Antimicrobial, antioxidant, anticancer, anti-inflammatory, antiplasmodial, antiviral, diuretic, and hepatoprotective <sup>[21]</sup>
<i>Nimba</i> ( <i>Azadirachta indica</i> A. Juss.)	Bark	One part	<i>In vitro</i> antiviral activity of bark extract against herpes simplex virus type-1 infection and antioxidant activity <sup>[22,23]</sup>
<i>Haridra</i> ( <i>Curcuma longa</i> L.)	Rhizome	One part	Antioxidant and antiviral <sup>[24,25,26]</sup>
<i>Vasa</i> ( <i>Justicia adhatoda</i> L.)	Whole part	One part	Antimicrobial, antioxidant, and cytotoxic properties <sup>[27,28]</sup>

Anti-HBV: Anti-hepatitis B virus

**Table 2: Composition of immune booster capsule**

Compound name	Composition/parts used	Proportion (%)	Properties
<i>Rasmanikya</i>	As <sub>2</sub> S <sub>3</sub>	5	Antioxidant property <sup>[29]</sup>
<i>Lakshmi Vilas Ras</i>	Compounds of Hg, Sn, S	5	Antioxidant property <sup>[29]</sup>
<i>Godanti Bhasma</i>	Incineration of herbo-mineral compound of CaSO <sub>4</sub> .2H <sub>2</sub> O	10	<i>Bhasm as Rasayana</i> <sup>[30]</sup>
<i>Sphatika Bhasma</i>	Incineration of KAl (SO <sub>4</sub> ) 2•12H <sub>2</sub> O	10	Hemostatic and anti-inflammatory properties <sup>[31]</sup>
<i>SudhaTankana</i>	Incineration of herbo-mineral compound of Na <sub>2</sub> [B <sub>4</sub> O <sub>7</sub> ].10H <sub>2</sub> O	10	Immune and antioxidant response <sup>[32-34]</sup>
<i>Pushkarmoola Churna</i> ( <i>Inula racemosa</i> Hook. F.)	Root	10	Cardioprotective and antioxidant properties <sup>[35]</sup>
<i>Madhuyasti Churna</i> ( <i>Glycyrrhiza glabra</i> L.)	Root	10	Antioxidant and enhancement of immunity anti-inflammatory, antiviral, antioxidant properties <sup>[26,36]</sup>
<i>Sitopaladi Churna</i>		30	Anti-allergic and mast cell stabilization effect <sup>[37]</sup>
<i>Haridra</i>	Rhizome	10	Antioxidant and antiviral <sup>[24,25,38]</sup>

### Sample size

A formal estimation of sample size was not done. However, we had decided to analyze suitable data from at least 1000 participants, hence collecting data of 1714 participants. Of these participants, only the data of 1003 participants were found to be eligible for this analysis.

### Statistical analysis

Data are presented as frequency, proportions (%), and median. The collected data were analyzed through the Statistical Package for the Social Sciences (SPSS) version 24 (IBM SPSS Statistics, Chicago, Illinois United State of America).

## Results

A total of 1714 participants received the AIBK treatment during the said period. Out of these, 1003 participants were

**Table 3: Details regarding characteristics of participants**

Characteristics of participant (baseline characteristics)	n (%)
Follow-up periods between the last dose of the medication and the interview date	
2 months	421 (42)
1 month and 3 weeks	488 (49)
1 month and 2 weeks	73 (7)
1 month and 1 week	12 (1)
<1 month and 1 week but >2 weeks	9 (1)
Age of participant (years)	
18-20	5 (0.5)
21-30	249 (24.8)
31-40	279 (27.8)
41-50	338 (33.7)
51-60	125 (12.5)
61-70	7 (0.7)
Sex of the participants	
Male	904 (90.1)
Female	99 (9.9)
Distribution of participants according to occupation	
Guards	17 (1.6)
Health professionals	69 (6.9)
Others	135 (13.5)
Police personals	782 (78.0)
Preexisting conditions in the participants prior to intake of medications	46 (4.6)
Influenza-like symptoms	
Cough and cold	30 (3.0)
Fever	8 (0.8)
Body ache	6 (0.6)
Headache	4 (0.4)
Weakness	3 (0.3)
Hypertension	3 (0.3)
DM2	2 (0.2)
Hemorrhoids	2 (0.2)
Constipation	2 (0.2)
Asthma	1 (0.1)
<b>Symptoms observed in participants after intake of kits</b>	
Adverse reaction observed by the participants	
Vertigo	1 (0.1)
Body ache	2 (0.2)
Headache	3 (0.3)
Excessive perspiration and burning sensation in body	15 (1.5)
Obstructed flow of urination/burning micturition	3 (0.3)
Acne	4 (0.4)
Gastrointestinal tract-related symptoms	
Aphthous ulcer	2 (0.2)
Nausea and vomiting	7 (0.7)
Acidity and burning sensation in abdomen	13 (1.3)
Diarrhea	4 (0.4)
Constipation	6 (0.6)
Bleeding per rectum	2 (0.2)

DM: Diabetes mellitus

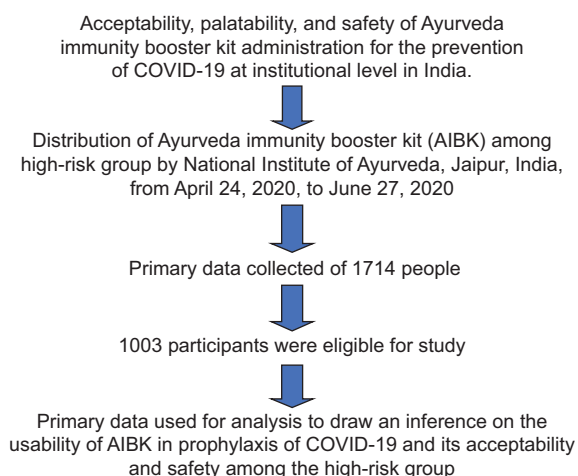
considered for safety, efficacy, and compliance data analysis. [Figure 1]

### Demographic results

In this study, the median age was 39 years (range, 1970). [Table 3] Only 0.7% (7 of 1003) participants were in the age group of 61 years and 70 years and comprise chemists and doctors. The majority of the participants were male, 90.1% (904 of 1003). A total of 78.0% of participants (782 of 1003) were police personnel. [Table 3] The 97.4% of participants (977 of 1003) had no issue with the palatability of AIBK. A total of 2.4% of participants (24 of 1003) were under quarantine while taking the AIBK as per government policy for quarantine at that time. All the other participants could be considered high-risk populations for COVID-19 as they were frontline workers directly exposed to COVID-19-positive patients or other high-risk populations. A total of 4.7% of participants (47 of 1003) had complained about the various difficulties in taking AIBK. A maximum of these (28 participants) were related to the bad palatability of immune booster *Kwatha* which was bitter in taste. The low feasibility to prepare this decoction from raw material was another issue related to this immune booster *Kwatha*. A total of 4.6% of participants (46 of 1003) were suffering from at least one comorbidity such as hypertension, diabetes mellitus 2, and/or other symptoms of cough, cold, headache, weakness, occasional throat irritation, fever, and hemorrhoids at the time of enrollment. [Table 3] A total of 4.3% of participants (43 of 1003) were tested for COVID-19 disease by reverse transcription–polymerase chain reaction methods as they were having some of the symptoms of cough, cold, headache, weakness, occasional throat irritation, and fever at the time of initiation of this immune booster kit and none was found to be positive for COVID-19. The rest of the participants did not report any previous disease or symptoms.

### Safety results

A total of 7.5% of participants (75 of 1003) reported having adverse events after taking the AIBK. These were acidity and burning sensation in the abdominal region, excessive perspiration and burning sensation in the body, diarrhea,



**Figure 1: Flowchart**

constipation, headache, body ache, acne, nausea and vomiting, mouth ulcer, the obstructed flow of urination or burning micturition, and vertigo. [Table 3] Most of these symptoms are related to the gastrointestinal tract. All these adverse events seemed to be related to study medications, and none of the adverse event reports was a serious adverse event or clinically significant. In most of the cases, these were self-limiting in nature and the rest events were resolved after adjustment of dose.

### Efficacy results

None of these participants had developed any COVID-19 and/or COVID-19-like symptoms up to 2 weeks of follow-up after completion of treatment.

### Discussion

This initiative was taken by the National Institute of Ayurveda as no published pre- and postexposure medications or vaccines were available at that time. The said Ayurvedic medications used in AIBK are in use for a long time for immunomodulation. These drugs possess *Rasayana* (immune modulation) properties which possibly helped in immune modulation and thus may be helpful in the prevention of COVID-19. The various Ayurveda treatment principles (like line of management of *Jwara* (fever), *Abhisangaja Jwara* (fever of infectious origin), *Visha Chikitsa* (anti-poisonous treatment), *Kasa* (cough), *Swasa* (dyspnea), *Rajyakshama* (a wasting disease indicting low immune response) diseases) might be useful in combating the COVID-19, were discussed for their usability in prevention of COVID-19.<sup>[39]</sup> Considering all these facts and with traditional and clinical experiences, a time-tested herbal and herbo-mineral formulation as AIBK was formulated. *Chyavanprasha* is well known worldwide for immunity modulation properties, and there is no concern for its safety. *Vyadhi Kshamatva Kwatha* comprised *Giloya* (*Tinospora cordifolia* (Willd.) Hook. F. and Thoms.),<sup>[5]</sup> *Nagarmotha* (*Cyperus rotundus* L.),<sup>[7,8]</sup> *Pittapapada* (*Justicia procumbens* L.),<sup>[20]</sup> *Triphala* (*Terminalia chebula* Retz. and Willd.) + (*Terminalia bellirica* Roxb.) + (*Emblica officinalis* Gaertn.),<sup>[9]</sup> *Raktachandana* (*Pterocarpus santalinus* L. F.),<sup>[11]</sup> *Tulsi* (*Ocimum sanctum* L.),<sup>[12]</sup> *Chirayata* (*Swertia chirayita* Roxb. Ex [Fleming] Karst.),<sup>[13,14]</sup> *Madhuyasti* (*Glycyrrhiza glabra* L.),<sup>[15]</sup> *Kutaki* (*Picrorhiza kurroa* Royle Ex Benth.),<sup>[16]</sup> *Kutaja* (*Holarrhena pubescens* [Buch.-Ham.] Wallich Ex Do),<sup>[17]</sup> *Karanja* (*Pongamia pinnata* L.),<sup>[18,19]</sup> *Nimba* (*Azadirachta indica* A. JUSS.),<sup>[22,23]</sup> *Haridra* (*Curcuma longa* L.),<sup>[24]</sup> *Vasa* (*Justicia adhatoda* L.),<sup>[27]</sup> and *Bhumyamalaki* (*Phyllanthus niruri* Sensu Hook. F. Non Linn.) in equal proportion. All these drugs may be helpful in immune modulation by their different properties. Some of these drugs – *Madhuyashti*, *Nimba*, *Haridra*,<sup>[25]</sup> *Vasa*,<sup>[28]</sup> *Triphala*,<sup>[10]</sup> *Giloya*,<sup>[6]</sup> and *Bhumyamalaki*<sup>[21]</sup> are also known to have antiviral effects. *Manahshila* ( $As_2O_3$ ), an arsenic ore, is considered *Rasayana* in *Ayurveda* and is useful in *Abhisangaja Jwara* and *Visha Chikitsa*.<sup>[40-42]</sup> *Vyadhikshamatva* capsule contains compounds of arsenic–*Rasmanikya* ( $As_2S_3$ ) and *Lakshmi Vilas Ras* (compounds of Hg, Sn, S)<sup>[29]</sup> which are

used for combating the hyperallergic conditions, *Kasa* (cough) and *Shwasa* (dyspnea). *Godanti Bhasma* (incineration of herbo-mineral compound of  $CaSO_4 \cdot 2H_2O$ ),<sup>[30]</sup> *Shuddha Tankana* (incineration of herbo-mineral compound of  $Na_2 [B_4O_7] \cdot 10H_2O$ ),<sup>[32-34]</sup> *Sphatika Bhasma* (incineration of  $KAl(SO_4) 2 \cdot 12H_2O$ ),<sup>[31]</sup> *Sitopladi Churna*,<sup>[37]</sup> *Pushkarmoola Churna* (*Inula racemosa* HOOK. F.),<sup>[35]</sup> *Madhuyasti Churna*,<sup>[36,26]</sup> and *Haridra Churna*<sup>[38]</sup> are added to prevent the COVID-19.

We had not observed any COVID-19-positive participants or symptoms of COVID-19 in participants during the follow-up. However, we cannot make any objective claims on the incidence of COVID-19 from this study, especially with no control group and the absence of COVID-19 testing in the interventional participants. None of the participants reported any serious adverse effects needing intensive medication or hospitalization of administration of the AIBK.

The acceptability of the AIBK was as high as 97.4% although some palatability-related issues were noted for immune booster *Kwatha*. The taste of immune booster *Kwatha* was very bitter. We can overcome this palatability issue by adding jaggery or honey in the prepared decoction or any acceptable ingredient to make it more palatable in all age groups. Acceptability of this *Kwatha* may also be affected by the *Prakriti* (body constitution), *Satmya* (homologous), *Satva* (mental strength), and *Samhanana* (body build) of the patients. Participants with *Pravara Samhanana* (optimum body build) generally have greater *Agnibala* (digestive power/strength) to withstand the higher doses. We had advised *Kwatha* in the dose of 40 ml twice a day to every participant, but this dose may also be proved slightly more for the participant of *Pittaja Prakriti* (*Pittaja* body constitution), *Avara Satva* (suboptimum mental strength), *Avara Satmya* (suboptimum conduciveness of the body), and *Avara Samhanana* (suboptimum body build) and delicate participants like a female. We observed that the issue of palatability of immune booster *Kwatha* was more related to females and with age of the participant. The palatability issues decreased with an increase in the age of the participants. Excessive perspiration or burning sensation in the abdomen was issued in some of the patients. [Table 3] Diarrhea, vomiting, headache, malaise, cramps, mouth ulcers, the obstructed flow of urination, and vertigo were also reported in a few of the participants. [Table 3] Some contents of the immune booster *Kwatha-Nagarmotha*<sup>[7,8]</sup> and *Raktachandana*<sup>[11]</sup> are also having hypoglycemic and antihypertensive effects. [Table 1] The hypoglycemic effect may be the reason that some participants felt excessive perspiration or burning sensation in the body, tingling sensation in the toe, vertigo, and headache. Diarrhea, vomiting, cramps, mouth ulcer, dyspepsia, and obstructed flow of urination were observed in these participants due to the prescribed dose, but none of these symptoms were serious in nature, and not needed any medication. In nutshell, the acceptability of these formulations in most of the participants was good. Generally, the immunity in the studied population may be somewhat compromised due to fatigue and stress

related to their work, especially in police personnel. There are disturbances in their routine natural urges, eating habits, etc., which can lead to compromised immunity. After taking AIBK, most of these participants reported that they felt better in terms of stamina and mental well-being. After analyzing the data of this study, it can hypothesize that AIBK may be effective in COVID-19 prevention.

### Limitations

As this is an open-label, nonrandomized single-arm self-assessed nondiagnostic study, hence the chances of bias are more toward the study medication. The control on assessment of study outcome is purely subjective and has no control of the investigator and/or diagnostic methods/procedures in assessing the outcome. Furthermore, the statistically powered sample size was also not determined.

### Conclusion

The *Ayurveda* immunity booster kit (AIBK) comprised *Chyavanprasha*, *Vyadhi Kshamatva Kwatha* and *Vyadhikshamatva* capsule was well tolerated with known mild adverse events, which were not severe in nature. None of the patients out of 1003 had COVID-19 and/or COVID-19-like symptoms during 2 weeks of follow-up after the completion of treatment.

Considering the unmet medical condition of COVID-19, the *Ayurveda* immunity booster kit can be used for prevention of COVID-19 along with all other safety measures of COVID-19 till the entire population of India gets vaccinated for COVID-19.

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### Conflicts of interest

There are no conflicts of interest.

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